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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,255	03/29/2001	Michael S. C. Fung	TNX 98-2-01	7231

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	17

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,255	FUNG ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) *38-41* is/are withdrawn from consideration.

5)☒ Claim(s) *29 and 30* is/are allowed.

6)☒ Claim(s) *22-28 and 31-35* is/are rejected.

7)☒ Claim(s) *36 and 37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed 4/17/03 (Paper No. 15) is acknowledged.
Claims 1-21 have been cancelled.
Claims 22-41 have been added and are pending.

Newly submitted claims 38-41 are directed to an invention that is independent or distinct from the invention originally claimed for the same reasons as set forth in Paper No. 12 with respect to claims 20-21.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-41 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 22-37 *are under consideration in the instant application.*

3. This Office Action will be in response to applicant's arguments, filed 4/17/03 (Paper No. 15). The rejections of record can be found in the previous Office Action (Paper No. 14).

It is noted that New Grounds of Rejection are set forth herein.

4. Applicant's cancellation of claims 1-19 has obviated the previous objections and rejections with respect to these claims.

Priority Claim

5. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). **The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications** except when the reference is to a prior application of a CPA assigned the same application number.

Appropriate correction is required.

Specification

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> *(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

9. Claims 22-26 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Pascuel et al. (J. Immunol. Methods 127:263-269, 1990, IDS #C9).

Applicant's arguments, filed 4/17/03, with respect to the rejection of record in Paper No. 14 as applied to the newly added claims have been fully considered but have not been found convincing.

As previously noted, Pascuel et al. teach a monoclonal antibody that binds Factor D and completely inhibits rabbit erythrocyte hemolysis by human serum as well as prevents the cleavage of C3 to C3b by cobra venom factor at a ratio of 80:1. (see entire article, especially the abstract). The claimed functional limitations would be inherent properties of the referenced antibodies, and one would expect at a ratio of less than 80:1, said monoclonal antibody would inhibit complement activation, though not completely. The claimed and referenced antibodies appear to have equivalent binding specificities. The burden is on the applicant to establish a patentable distinction between the claimed and referenced antibodies. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

Applicant has argued that because *complete* blockade of human factor D required a molar ratio of MAb to Factor D of 80:1, the instant claims requiring a ratio of 1.5:1 are not anticipated because the recited ratio requires a binding affinity that is not inherent in the referenced antibodies.

However, it is noted that the instant claims do not require that the antibody *completely inhibit* complement activation at a particular ratio.

Therefore the reference appears to anticipate the claimed invention.

The rejection of record is therefore maintained as applied to the newly added claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

11. Claims 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pascuel et al. (J. Immunol. Methods 127:263-269, 1990, IDS #C9) in view of standard techniques in the art at the time the invention was made as evidenced by Janeway et al. (Immunolobiology, 3rd edition, Current Biology Ltd, London, England 1997 page 13:7-8, of record).

Applicant's arguments, filed 4/17/03, with respect to the rejection of record in Paper No. 14 as applied to the newly added claims have been fully considered but have not been found convincing.

Applicant argues that Pascuel et al. do not teach an antibody with the instantly recited properties, and therefore does not provide an appropriate basis for the obviousness rejection of record.

Applicant's arguments and the teachings of Pascuel et al. have been discussed supra.

Pascuel et al. teach as above.

Pascuel et al. do not teach a chimeric, humanized, deimmunized or human form of the antibody or cell line producing said antibody.

Janeway et al. teaches standard techniques in the art at the time the invention was made including that humanized antibodies comprise the CDRs of a mouse monoclonal antibody onto the human framework of a human immunoglobulin, and that said chimeric antibodies are far less immunogenic in humans than the parent mouse monoclonal antibodies, and thus they can be used for treatment of humans with far less risk of anaphylaxis than the parent non-human monoclonal antibodies. For similar purposes, monoclonal antibodies that are entirely human in origin can be made in mice lacking endogenous immunoglobulin genes.

Therefore, one of ordinary skill in the art at the time the invention was made, who wanted to decrease the negative effects of complement in patients with pathological inflammation and autoimmune disease, would have been motivated to make and use the chimeric and/or human form and recombinant cell lines thereof, taught by Janeway et al. of the monoclonal antibodies taught by Pascuel et al. as an inhibitor of complement activation because Janeway et al teaches that humanized antibodies are far less immunogenic in humans and have far less risk of anaphylaxis and because Pascuel teaches a monoclonal antibody that binds Factor D and inhibits complement activation.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

One of ordinary skill in the art at the time the invention was made would have been motivated to use the chimeric form of the monoclonal antibodies taught by Pascuel et al as an inhibitor of the alternate pathway of complement activation because Janeway et al teaches that humanized antibodies are far less immunogenic in humans and have far less risk of anaphylaxis.

The rejection of record is therefore maintained as applied to the newly added claims.

12. Claims 27, 32 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pascuel et al (J. Immunol. Methods 127:263-269, 1990, IDS #C9) in view of U.S. Patent No. 5,861,156 (of record).

Applicant's arguments, filed 4/17/03, with respect to the rejection of record in Paper No. 14 as applied to the newly added claims have been fully considered but have not been found convincing.

Applicant argues that Pascuel et al. do not teach an antibody with the instantly recited properties, and therefore does not provide an appropriate basis for the obviousness rejection of record.

Applicant's arguments and the teachings of Pascuel et al. have been discussed supra.

Pascuel et al. teach as above.

Pascuel et al. do not teach the recited antibody fragments nor a cell line that produces said fragments.

'156 teaches in Column 10, lines 42-62, that the complete antigen binding site of an antibody may be obtained by recombinant methods from monoclonal antibodies or combinatorial libraries, and may correspond to the two-chain 50 kD Fab or related Fab' fragments, the two-chain 25 kD Fv fragment, or the 26-27 kD single-chain Fv. '156 teaches that all of these species are smaller and far more rapid in biodistribution than IgG monomers or dimmers and that their reduced size is advantageous for primary targeting.

Therefore, one of ordinary skill in the art at the time the invention was made, who wanted to decrease the negative effects of complement in patients with pathological inflammation and autoimmune disease, would have been motivated to make and use the Fab, $F(ab)_2$, Fv or ScFv forms and recombinant cell lines thereof, taught by '156 of the monoclonal antibodies taught by Pascuel et al. as an inhibitor of complement activation because '156 et al teaches that antibody are smaller and far more rapid in biodistribution than IgG monomers or dimmers and that their reduced is advantageous for primary targeting, and because Pascuel teaches a monoclonal antibody that binds Factor D and inhibits complement activation.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

13. Claims 29-30 appear to drawn to allowable subject matter.

14. Claims 36-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Applicant's request for rejoinder of claims 38-41 is acknowledged. However, the instant method claims are not commensurate in scope with an allowable product, and therefore are not at present eligible for rejoinder practice.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
June 26, 2003

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